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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,883

09/07/2006

Mark Denison

VBLT:038US/10511181

1352

32425 7590 03/24/2008
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EXAMINER

KINSEY WHITE, NICOLE ERIN

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

03/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,883	Applicant(s) DENISON, MARK	
	Examiner NICOLE KINSEY WHITE	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 2-5 and 10-11, drawn to the technical feature of a live, attenuated Coronaviridae.

Group II, claims 6-8, drawn to the technical feature of a live, attenuated Arteriviridae.

Group III, claims 17-20 and 25-26, drawn to the technical feature of inducing an antiviral immune response by administering a live, attenuated Coronaviridae.

Group IV, claims 21-23, drawn to the technical feature of inducing an antiviral immune response by administering a live, attenuated Arteriviridae.

Group V, claim 34, drawn to the technical feature of a nidovirus genome.

Group VI, claim 35, drawn to the technical feature of a nidovirus replicase.

Claims 1, 9, 12-15, and 36-40 link inventions I and II and claims 16, 24 and 27-33 link inventions III and IV. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claims. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions **shall** be withdrawn and any claims depending from or otherwise requiring all the limitations of

the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The shared technical feature of Groups I-IV is a live attenuated Nidovirus with a replicase comprising at least one proteinase cleavage site with reduced or no cleavage.

The technical feature of Group V is a Nidovirus genome.

The technical feature of Group VI is a Nidovirus replicase.

There is no shared technical feature between Groups I-IV, Group V and Group VI. Therefore, Groups I-IV, Group V and Group VI lack unity with one another. The technical feature shared among the inventions listed as Groups I-IV is a live attenuated

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Nidovirus with a replicase comprising at least one proteinase cleavage site with reduced or no cleavage. The noted shared technical feature does not provide a contribution over the prior art, as evidenced by the teachings of Bonilla et al. (Virology, 1995, 209:489-497). Bonilla et al. discloses a murine hepatitis virus that contains a deletion at cleavage sites p28-p65. The virus of Bonilla et al. exhibits reduced or no cleavage at the cleavage site (see the abstract, Table 1 and Figure 6). Hence, in the absence of a contribution over the prior art, the noted shared technical feature is not a shared special technical feature. Without a shared special technical feature, the inventions listed as Groups I-IV lack unity with one another.

Further Restriction

If applicants elect Group I or III, applicants are further required to elect one of the following:

- a) Coronavirus, or
- b) Torovirus.

If applicants elect Coronavirus, applicants are required to elect **one** of the following groups:

- c) avian infectious bronchitis virus,
- d) bovine coronavirus,
- e) canine coronavirus,
- f) feline infectious peritonitis virus,
- g) human coronavirus 229E and human coronavirus OC43,
- h) murine hepatitis virus,

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- i) porcine epidemic diarrhea virus, porcine hemagglutinating encephalomyelitis virus, and porcine transmissible gastroenteritis virus,
- j) rat coronavirus,
- k) turkey coronavirus,
- l) severe acute respiratory syndrome virus, or
- m) rabbit coronavirus.

Each virus group (coronavirus vs. torovirus) and each coronavirus is patentably distinct, because each virus is different with different sizes, serotypes, natural hosts, diseases, pathology, etc. **This is not a species election.**

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

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require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Stacy B. Chen/
Primary Examiner, Art Unit 1648

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/553,883	DENISON, MARK	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	